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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,491	04/18/2006	Wenping Wu	10178.204-US	3823
25908 7590 09/18/2009 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary

Application No.

10/576,491

Applicant(s)

WU ET AL.

Examiner

SHERIDAN SWOPE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-45 is/are pending in the application.
- 4a) Of the above claim(s) 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☒ Claim(s) 29-44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' request for continued examination of July 24, 2009, in response to the action of April 24, 2009, is acknowledged. It is acknowledged that Claims 1-5, 7, 11-14, 16-20, 23-25, 27, and 28 have been cancelled and Claims 29-45 have been added. Claims 29-45 are pending. The elected invention is directed to the protease polypeptide of SEQ ID NO: 2 and variants thereof. Claim 45 is withdrawn as being directed to non-elected subject matter. Claims 29-44 are encompassed by the elected inventions and are hereby examined.

Priority

The priority date granted for Claims 29-39 and 42-44 is October 22, 2004, the filing date of PCT/DK04/00730, which disclosed the elected invention. No priority date is granted for Claims 40 and 41, as said claims introduce New Matter; see below.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claims 29-35, the phrase "with more than xx% sequence identity" renders the claim indefinite. It is unclear whether said phrase means "consisting of more than xx% sequence identity" or "comprising more than xx% sequence identity". The skilled artisan would not know the metes and bounds of the recited invention. Claims 36-44, as dependent from Claim 29, are

indefinite for the same reason. For purposes of examination, it is assumed that “with more than xx% sequence identity” means “consisting of more than xx% sequence identity”.

For Claim 42, the phrase “variant protease” renders the claim indefinite. It is unclear whether said phrase means “variant of the protease set forth by residues 1-226 of SEQ ID NO: 2” or “some other type of variant”. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that “variant protease” means “variant of the protease set forth by residues 1-226 of SEQ ID NO: 2”.

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Written Description

Claims 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 40 and 41 introduce the limitation of 50% and 55%, respectively, residual activity after storage for 30 minutes at 35°C. The specification fails to describe the limitation of storage for 30 minutes at 35°C and, thus, Claims 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1-5, 7, 11-13, 24 and 28 under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994, for the reasons explained in the prior action, is withdrawn because said claims have been cancelled.

Claims 29-39, 42, and 43 are herein rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994, for the same reasons. In so far as the protease of SEQ ID NO: 2 has 50% and/or 55% residual activity after storage for 30 minutes at 35°C, Claims 40 and 41, respectively, are herein rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994, for the same reasons.

In support of their request that the prior rejection be withdrawn, Applicants provide the following arguments, which are relevant to the current rejection.

(A) After the filing of Isono et al, Takeda disclosed the amino acid sequence of Isono's alkaline protease in US5,543,322 and Morita et al., 1994. The characteristics of the alkaline protease described in the '322 patent and Morita et al. are consistent with the characteristics of the alkaline protease described in Isono et al. Thus, persons of ordinary skill in the art would expect that the alkaline protease described in the '322 patent and Morita et al. is the same protease described in Isono et al.

(B) The proteases described in Isono et al. are alkaline proteases, which belong to a different class of protease than trypsin-like proteases such as the protease of SEQ ID NO: 2 of the present invention.

(C) A comparison of the amino acid sequences of the Isono et al. alkaline protease and SEQ ID NO: 2 of the present application shows that the two sequences are not homologous.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Both US5,543,322 and Morita et al characterized a protease from *Fusarium* sp. S-19-5 (IFO 8884), which is a different strain than the one used by Isono et al (IFO 5232).

Isono et al provided no characterization of the proteases isolated from *F. solani* (Table 5; IFO 5232). In fact, although Isono et al assert that they identified alkaline proteases from a variety of *Fusarium* species, no evidence was provided that any of the proteases isolated from *F. solani* were alkaline proteases.

More importantly, the evidence provided in Table 5 of Isono et al was obtained using a culture supernatant, which would contain all proteases produced by the *F. solani* strain, the same strain used by Applicants. Thus, the skilled artisan would believe that, more likely than not, said isolate of Isono et al included the protease set forth by SEQ ID NO: 2 herein.

(B) Reply: The evidence provided in Table 5 of Isono et al was obtained using a culture supernatant and casein as a substrate. Trypsin-like proteases cleave after any lysine or arginine, including those in casein. Thus, the evidence provided in Table 5 of Isono et al does not differentiate between alkaline or trypsin-like proteases. Also, see (A), above.

(C) Reply: It is unclear to the Examiner what sequence of Isono et al is being compared to SEQ ID NO: 2 herein. Isono et al discloses no sequences. It is assumed that Applicants are referring to the sequences disclosed by US5,543,322 and Morita et al. As

explained above, both US5,543,322 and Morita et al characterized a protease from *Fusarium* sp. S-19-5 (IFO 8884), which is a different strain than the one used by Isono et al (IFO 5232).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 in view of Okuda et al, 2004 (FD 12-MAR-2003), for the reasons explained in the prior action, is withdrawn because said claims have been cancelled.

Claim 44 is herein rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 in view of Okuda et al, 2004 (FD 12-MAR-2003), for the same reasons.

In support of their request that the prior rejection be withdrawn, Applicants provide the following assertion, which is relevant to the current rejection.

(A) Okuda et al. discloses a detergent composition comprising an alkaline protease and one or more other enzymes. However, Okuda et al do not teach or suggest the proteases of the present invention.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that Okuda et al do not teach the protease of SEQ ID NO: 2. If Okuda et al did so teach, this would be a rejection under 35 U.S.C. 102(b), not 35 U.S.C. 103(a).

As acknowledged by Applicants, Okuda et al teach what was well known in the art; detergent compositions comprising one or more proteases and additional hydrolytic enzymes.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652